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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,639	05/21/2001	Doris Huebler	1565	3031

7590 04/14/2003

Michael J Striker
103 East Neck Road
Huntington, NY 11743

EXAMINER
CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
1615	11

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	09/806,639	HUEBLER ET AL.	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- Th MAILING DATE of this communication appears on the cover sheet with the corr spondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of request for extension of time, amendment A, dated 12-2-02 and prior art with attachment, dated 1-13-03 is acknowledged.

Claims 1-6 have been canceled and new claims 7 to 31 have been added.

Claim Rejections - 35 USC § 103

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voorspoels et al (hereafter Voorspoels).

Voorspoels teaches bioadhesive tablets comprising testosterone and its esters for buccal administration. Testosterone and its esters i.e., acetate, propionate, enanthate and decanoate of Voorspoels meet the claim requirement of testosterones esters with 1-20 carbon atoms in the carboxylic acids radical (page 1228, col. 2, 1st paragraph and table 1). Instant claim requires administration of a mixture of testosterone and testosterone ester in a ratio of 1:100 to 1:1. Voorspoels teaches buccal administration of testosterone and testosterone esters separately and not a combination. Further, Voorspoels studied the bioavailability of buccal tablets in dogs, as opposed to instant claims, which recite a person. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine testosterone and its esters of Voorspoels in one composition and administer them via buccal route because Voorspoels teaches these compounds independently for simulating the circadian rhythm of testosterone plasma levels. It is obvious to combine two compositions taught by prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose to form a third composition to be useful for the very same purpose. In re Kerkhoven,

626 F.2d 846, 205 USPQ 1069 (CCPA 1980). Accordingly, one of an ordinary skill in the art would have expected to achieve an additive effect in simulating circadian rhythm by combining testosterone and esters of testosterone. Further, Voorspoels discussed the various routes of administration of testosterone and its esters, in men, for maintaining circadian rhythm (introduction). Accordingly, it would have been obvious for one of an ordinary skill in the art to administer testosterone and its esters to human beings with an expectation to maintain testosterone levels and stimulate circadian rhythm. With respect to the claimed ratios, optimizing the amounts of components to achieve art recognize effect is within the scope of a skilled artisan.

Claims 7-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voorspoels et al (hereafter Voorspoels) in view of US 6,063,404 to Timpe et al (hereafter Timpe).

Voorspoels, discussed above, fails to teach a bi-layer buccal tablet. Voorspoels states that the low bioavailability of testosterone esters could be due to the absence of a backing layer and desire a bioadhesive tablet for larger buccal mucosal surface for the absorption of the drug.

Timpe teaches an oral bioadhesive tablet containing at least one bioadhesive adjuvant and at least one lubricant and pharmaceutically active agent. The bioadhesive component is selected from compounds such as cellulose, carboxyvinyl polymer, etc., and lubricant selected from talc, metallic soap, fatty acid mixture etc (col. 3). Further, the tablet is made of 2 layers comprising an active agent layer and a bioadhesive layer. Example 3 (col. 6) particularly recites testosterone ester in the active agent layer. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the buccal tablet (containing testosterone

and its esters) as a bi-layered tablet by incorporating an adhesive layer over the active agent-containing layer because Timpe teaches that the bioadhesive layer protects the active agent from microbial attack and also provide a large contact area in the buccal mucosa. Accordingly, a skilled artisan would expect to achieve a complete resorption of the active agent (testosterone and its esters) across the oral mucosa because of the bioadhesive layer. With respect to the claimed spray-drying process, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process Claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Further, applicants have not provided any comparative data to show the criticality of the process for preparing the claimed product.

Response to Arguments

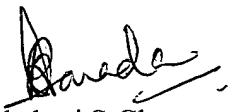
Applicant's arguments filed 12-2-02 have been fully considered but they are not persuasive. Applicants argue that Voorspoels does not teach a method of controlling testosterone levels in serum by administering a mixture of testosterone and its esters. However, as explained in the previous action, even though the reference does not teach a particular combination, the references recognizes both the compounds for the same utility and accordingly, combining two components used for the same utility with an expectation to achieve at least an additive effect would have been obvious for a skilled artisan. Applicants argue that Voorspoels teaches testosterone to be more effective than its ester, which is teaching away from the instant claims.

This argument is not persuasive because instant claims do not state the amount of absorption of testosterone or its esters, as argued. Yet the combination of testosterone (with absorption) and testosterone ester (low absorption) would still result in an increased absorption over testosterone alone. Furthermore, Voorspoels clearly state that the low absorption seen could be due to high lipophilicity and that optimal lipophilicity is important for the solubility of the drug (page 1231). Accordingly, choosing a testosterone ester with optimal lipophilicity that provides the desired solubility and thus bioavailability of the drug is within the scope of a skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
April 11, 2003